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DE 197 16 051 A 1

Application disclosed with the consent of the applicant according to 5 31 Par. 2 Sect. 1 Patent Act

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(54) Resorbable, screw-on luxation retaining ring for socket components of hip prostheses

(57) Dislocation (luxation) of an artificial hip joint is one of the most frequent early complications after provision with a hip prosthesis. The resorbable luxation securing ring (A), made of the material PLLA (poly-L lactic acid), prevents dislocation during the healing phase, and is transformed into yielding connective tissue, which reduces the risk of a luxation also over the long term. That eliminates the risk of a material failure or a restriction of mobility in the hip joint, as would exist in the case of a non-resorbable substance.

The luxation retaining ring is screwed onto the edge of the socket component (B) with three also resorbable screws (C) (PLLA), and surrounds the prosthesis head (E) in such a way that the latter is captured by it in the socket. The luxation retaining ring has corresponding prepared bored holes (G) to receive the screws. Ring and screws are made of PLLA (poly-L lactic acid). The ring is made in thicknesses of 1/2 and 1 cm, corresponding to the dimensions of the particular socket edge. The ring covers the edge of the socket (B) with a 210-degree cutout, and thus can be placed as desired to meet all requirements.

The resorbable luxation retaining ring, made of the material PLLA (poly-L lactic acid), is suitable for all common commercial hip prostheses socket components and socket inlays made of plastic with a wall thickness of at least 0.5 cm.

[See original for diagram.]

The following information is taken from documents submitted by the applicant.

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Description

The invention concerns an add-on ring of PLLA (poly-L lactic acid) which is placed on the edge of socket components of hip prostheses made of plastic, using screws that are also made of PLLA.

With conventional socket components of hip prostheses which are installed in the pelvis (D), there is the danger that dislocation of the prosthesis head (E) from the socket (B) may occur. On the other hand, the luxation retaining ring surrounds the femoral head after the latter is placed in the socket and is kept in place by the screws and by way of a rounding that follows the curvature of the particular socket component or inlay. That prevents dislocation. In hip prostheses, the prosthesis head is usually anchored in the femur (F) through the prosthesis shaft. While other models of socket components or inlays of hip sockets made of a single piece sometimes have an edge that surrounds the prosthesis head (so-called snap sockets), they are for exactly that reason in significantly greater danger of becoming loose in their anchoring in the pelvis (D) because of the constant absorption of pressure during movements.

The resorbable material PLLA on the one hand eliminates the danger of a material failure (loosening/breaking of the screws or shearing of the socket ring when the prosthesis head frequently strikes the edge). On the other hand, after about 6 weeks the ring and attaching screws are transformed into flexible native connecting tissue, which provides protection against dislocations, for example in accidents or falls, even long-term.

Look-up location for PLLA: Clinical Orthopaedics and Related Research, 298, pp. 227-285, (1994), H. Pihlajamäki, O. Böström, M. Manninen: Absorbable Plugs of Self-Reinforced Poly-L-Lactic-Acid in the Internal Fixation of Rabbit Distal Femoral Osteotomies.

The luxation retaining ring (A) includes a 210-degree circular cutout, making it possible to be fixed on the edge of a plastic socket component (B) as desired and depending on the direction of dislocation at risk. To that end it has pre-bored holes (G) to receive Phillips screws (C) with sunken heads. The ring runs out gently toward both ends, so that no step formation occurs toward the margin of the plastic socket.

The luxation retaining ring of resorbable PLLA constitutes a significant improvement over the available socket components of hip prostheses in that the risk of the typical complication of a dislocation is reduced. The resorbability and transformation into flexible native connecting tissue also results in long-term protection against dislocations, without that foreign materials of the ring remain in the body, which otherwise could fail with constant use because of their rigidity.

Description of the drawings

Figure 1: Section through the artificial hip joint with luxation retaining ring in the transverse axis of the body

Figure 2: Enlarged cutout of Figure 1 with screw inserted

Figure 3: Side view of socket component with luxation retaining ring in position

Figure 4: Top view of socket component with luxation retaining ring in position

The meanings of the reference letters are:

- A luxation retaining ring
- B socket component
- C screws
- D pelvis
- E prosthesis head
- F femur
- G bored holes in the ring

Claims

1. A luxation retaining ring for socket components of hip prostheses or inlays thereof made of plastic, characterized by the fact that the luxation retaining ring (A) extends the particular socket rounding and curvature and hence surrounds the artificial femoral head. The luxation retaining ring is fixed on the socket component (B) or the inlay made of plastic with screws (C) and has corresponding bored holes (G) for that purpose.

2. The luxation retaining ring as recited in Claim 1, characterized by the fact that the luxation retaining ring consists of a 210-degree cutout. The ring tapers downward toward the ends, so that no step formation occurs toward the socket component.
3. The luxation retaining ring as recited in Claim 1 or 2, characterized by the fact that luxation retaining ring and attaching screws are made of PLLA (poly-L-lactic acid), which are resorbed after about 6 weeks and transformed into connective tissue.
4. The luxation retaining ring as recited in one of Claims 1 or 2 or 3, characterized by the fact that the luxation retaining ring exists in thicknesses of $\frac{1}{2}$ cm and 1 cm.

Accompanied by 1 page(s) of drawings

PCT/US G3/10950

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/32 A61F2/34 A61F2/30

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data bases consulted during the international search (name of data bases and, where practical, search terms used)

EPO-internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 197 16 851 A (KLUEBER DIETRICH DR MED) 13 November 1997 (1997-11-13) the whole document	1-5,27, 28 5,7-15, 17,21, 29-35
Y	US 5 735 981 A (BAEGE ROLAND ET AL) 7 April 1998 (1998-04-07) column 2, line 66 - column 3, line 9	5,17,21
Y	DE 32 09 348 A (HOMMEDICA INT INC) 23 September 1982 (1982-09-23) page 6, paragraph 2 page 10, paragraph 2 - page 11, paragraph 1 figure 1	7-15, 29-35
		-/-

 Further documents are listed in the continuation of box C. Patent family members are listed in annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the International filing date
- "L" document which may throw doubt on priority, claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "C" document relating to an oral disclosure, use, exhibition or other means
- "P" document published prior to the International filing date but later than the priority date claimed

- "T" later document published after the International filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "C" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "V" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "B" document member of the same patent family

Date of the actual completion of the international search

23 July 2003

Date of mailing of the international search report

10.12.03

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INTERNATIONAL SEARCH REPORT

International Application No.
PCT/US 03/10950

C(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 02 09615 A (BURROUGHS BRIAN R ;HARRIS WILLIAM H (US); HOEFFEL DANIEL P (US); M) 7 February 2002 (2002-02-07) page 14, line 17 - page 15, line 28 ----- US 5 997 582 A (WEISS JAMES M) 7 December 1999 (1999-12-07) the whole document ----- WO 00 13615 A (LANKA LIMITED ;BRUCE INGRID (SE); BRUCE LARS (SE)) 16 March 2000 (2000-03-16) the whole document -----	7-18, 12-14, 29-32, 34,35
A		24-26
A		24-26

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INTERNATIONAL SEARCH REPORT

International Application No.
PCT/US 03/16950

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: 99-103 because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentence of Rule 5.4(a).

Box II Observations where utility of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

see additional sheet

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-38

Remark on Protest

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

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International Application No. PCT/US 63/10950

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 218

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-38

A prosthetic constraining device for, or in combination with, a hip joint, comprising a ring for maintaining the ball joint coupling wherein the ring is made from a biologic and/or reabsorbable material.

2. claims: 39-52, 79-89

A prosthetic constraining device for use with a hip joint, comprising an arcuate body with a central opening wherein the distal surface of the arcuate body has a depression extending radially thereacross, and the proximal surface is adapted to be mounted to an acetabular prosthesis or natural bone.

3. claims: 53-78, 104-108

A constraining device for maintaining engagement of a prosthetic hip joint made from a biologic and/or absorbable material.

International Application No. PCT/US 93/10950

FURTHER INFORMATION CONTINUED FROM PCT/SA/ 210

Continuation of Box I.1

Claims Nos.: 90-103

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

INTERNATIONAL SEARCH REPORT

Information on patent family members

International
Ident No
PCT/US 03/10950

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
DE 19716851	A 13-11-1997	DE	19716851 A1	13-11-1997
US 5735981	A 07-04-1998	EP AT DE ES US	0649326 A1 188685 T 59389928 D1 2142348 T3 5725598 A	01-03-1995 15-01-2999 17-02-2996 16-04-2998 19-03-1998
DE 3200340	A 23-09-1982	DE	3200340 A1	23-09-1982
WO 0209615	A 07-02-2002	AU CA EP WO US	7697581 A 2416256 A1 1304988 A2 0209615 A2 2003058783 A1	13-02-2002 07-02-2002 02-05-2003 07-02-2002 13-03-2003
US 5997582	A 07-12-1999	AU AU BR CA EP HU JP NO PL WO US ZA	748766 B2 3758999 A 9910196 A 2330957 A1 1879776 A1 0182664 A2 2002513638 T 20005374 A 343731 A1 9956674 A1 6118211 A 200005956 A	13-06-2002 23-11-1999 26-12-2000 11-11-1999 07-03-2001 28-11-2001 14-05-2002 02-01-2001 10-09-2001 11-11-1999 29-08-2000 23-05-2001
WO 0013615	A 16-03-2001	SE AU AU BR CA CN EP JP NO SE WO US ZA	515572 C2 743913 B2 6816599 A 9913579 A 2343366 A1 1316891 T 1112046 A1 2002524137 T 20011178 A 9803078 A 0013615 A1 6565606 B1 200102000 A	03-09-2001 07-02-2002 27-03-2000 22-05-2001 16-03-2000 10-10-2001 04-07-2001 06-08-2002 08-03-2001 10-03-2000 16-03-2000 20-05-2003 12-09-2001

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